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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,528	10/13/2000	David M. Stern	0575/62096/JPW/JML	8939

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	PAPER NUMBER
1633	6

DATE MAILED: 01/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/687,528	STERN ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 8, 9 and 11-16, drawn to a method for inhibiting new tissue growth or neointimal formation in blood vessels in a subject, or for preventing exaggerated restenosis in a diabetic subject by administering an inhibitor of receptor for advanced glycation endproduct (RAGE) to said subject, wherein said inhibitor is a polypeptide, classifiable in classes 514 and 530, subclasses 2 and 350, respectively.

II. Claims 1-5, 7 and 11-16, drawn to a method for inhibiting new tissue growth or neointimal formation in blood vessels in a subject, or for preventing exaggerated restenosis in a diabetic subject by administering an inhibitor of receptor for advanced glycation endproduct (RAGE) to said subject, wherein said inhibitor is an organic or inorganic molecule, classified in class 514, subclass 1.

III. Claims 1-5, 8 and 11-16, drawn to a method for inhibiting new tissue growth or neointimal formation in blood vessels in a subject, or for preventing exaggerated restenosis in a diabetic subject by administering an inhibitor of receptor for advanced glycation endproduct (RAGE) to said subject, wherein said inhibitor is a nucleic acid, classifiable in classes 514 and 536, subclasses 44 and 23.1, respectively.

IV. Claims 1-6 and 10-16, drawn to a method for inhibiting new tissue growth or neointimal formation in blood vessels in a subject, or for preventing exaggerated

restenosis in a diabetic subject by administering an inhibitor of receptor for advanced glycation endproduct (RAGE) to said subject, wherein said inhibitor is an antibody, classified in class 424, subclass 130.1.

V. Claims 17, 18 and 22-24, drawn to a method for determining whether a compound inhibits new tissue growth in a blood vessel in a subject by administering the compound to a non-human animal and comparing new tissue growth or neointimal formation in an injured blood vessels in the animal with or without the administration of said compound, wherein the compound is an organic or inorganic molecule, classified in class 435, subclass 4.

VI. Claims 17, 19, 20 and 22-24, drawn to a method for determining whether a compound inhibits new tissue growth in a blood vessel in a subject by administering the compound to a non-human animal and comparing new tissue growth or neointimal formation in an injured blood vessels in the animal with or without the administration of said compound, wherein the compound is a polypeptide, classified in class 435, subclass 7.2.

VII. Claims 17, 19 and 22-24, drawn to a method for determining whether a compound inhibits new tissue growth in a blood vessel in a subject by administering the compound to a non-human animal and comparing new tissue growth or neointimal formation in an injured blood vessels in the animal with or without the

administration of said compound, wherein the compound is a nucleic acid, classified in class 435, subclass 6.

VIII. Claims 17 and 21-24, drawn to a method for determining whether a compound inhibits new tissue growth in a blood vessel in a subject by administering the compound to a non-human animal and comparing new tissue growth or neointimal formation in an injured blood vessels in the animal with or without the administration of said compound, wherein the compound is an antibody, classified in class 435, subclass 7.1.

Claims 1-5 and 11-16 link(s) inventions I-IV. Claim 6 links inventions I and IV. Claim 8 links inventions I and III. Claims 17 and 22-24 link inventions V-VIII. Claim 19 links inventions VI and VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6, 8, 11-17, 19 and 22-24. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are distinct from each other because they are drawn to methods of using different materials having different chemical structures, different physical properties, and different biological functions: polypeptides, organic or inorganic molecules, nucleic acids and antibodies. Further, they are drawn to methods that differ at least in method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. The differences between Inventions I-IV are further underscored by their different classifications and independent search status. Thus, they are patentably distinct from each other. Similarly, inventions V-VIII are distinct from each other because of the reasons as set forth above.

Inventions I-IV and inventions V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.E.P.. § 806.04, M.E.P.. § 808.01). In the instant case the different inventions have different modes of operation and have different functions. A method of inhibiting new tissue growth or neointimal formation or preventing exaggerated restenosis in a subject is different from a method for determining whether a compound inhibits new tissue growth in a blood vessel in a subject, and they differ at least in their objectives, method steps, reagents and/or dosages used, schedules, response variables, and criteria for success. The differences between Inventions I-IV and inventions V-

VIII are further underscored by their different classifications and independent search status. Thus, they are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.